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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,869	03/04/2004	Hubert Jansen	06478.1500	5244
22852	7590	09/09/2010		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 09/09/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/791,869

**Applicant(s)**

JANSEN ET AL.

**Examiner**

Philip R. Wiest

**Art Unit**

3761

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

In the reply filed 6/22/10, applicant cancelled claims 12-39 and added new claims 40-52. Claims 40-52 are currently pending.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
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1. Claims 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dudar et al. (US 5,211,638) in view of Larson (US 3,977,555).
  2. With respect to Claims 40-42, 44, and 48, Dudar et al. (hereafter 'Dudar') teaches a fluid transfer device comprising a lid portion 740 and an edge portion 738 formed integrally with said edge portion to form a receiving cap, and a piercing mandrel

(754, 756) formed integrally therewith. The piercing mandrel comprises a piercing portion configured to pierce completely through the thickness of an elastic stopper (see Figures 34-36), said piercing portion comprising a pointed end 756 and a substantially cylindrical portion 738 (Column 12, Lines 39-50). Regarding Claim 42, the edge portion comprises an inward projection (764a-d) configured to center the bead as the bead is received within the interior space. Dudar teaches the device substantially as claimed, but does not specifically teach a conical sealing portion proximal of the piercing portion for sealing tears in the elastic stopper of the vial.

Larson teaches a vial adapter for transferring medical fluids comprising a piercing mandrel for puncturing the septum of a medical vial. The piercing mandrel comprises a piercing portion at the distal end thereof, said piercing portion comprising a pointed tip 40 and a cylindrical portion 38 of constant diameter. The piercing mandrel further comprises a sealing portion 66 disposed proximal of the piercing portion, the sealing portion comprising an enlarged diameter that adjoins the cylindrical portion 38 and widens towards the lid portion (i.e. the sealing portion is substantially conical). The enlarged sealing portion serves to stretch the elastic stopper so as to ensure complete penetration by the needle-like piercing portion (see abstract). This system also causes the enlarged diameter portion to be pressed firmly against the stopper, thereby creating a seal between the sealing portion and the stopper. The use of an enlarged sealing portion on the proximal portion of a piercing mandrel is therefore known in the art. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the piercing mandrel of Dudar with Larson's enlarged sealing portion so as to

ensure complete penetration of an elastic stopper when a medical fluid container is inserted into the interior space.

3. With respect to Claim 43, Dudar teaches that the inward projection is further configured to engage the behind portion of the bead when the bead is substantially disposed in the space (see Figure 36).
4. With respect to Claims 45 and 46, Dudar teaches that the piercing mandrel is stationary relative to the lid portion. The inward projection radially surrounds the piercing mandrel (see Figures 34 and 35).
5. With respect to Claim 47, at least a portion of the piercing portion is disposed further away from the lid portion than the inward projection.
6. With respect to Claims 49 and 50, at least a portion (742, 746, and 748) of the edge portion extends away from the lid portion and inward projection. Specifically, the vial slots (766a-b) extend away from the inward projection along a direction that is parallel to the central longitudinal axis of the internal space. See Figures 35 and 36.
7. With respect to Claims 51 and 52, Dudar teaches that the free edge (746, 748, 766) has inner and outer diameters that are larger than the outer diameter of the rest of the edge portion.

### ***Response to Arguments***

Applicant's arguments with respect to claims 40-52 have been considered but are moot in view of the new ground(s) of rejection.

Further, applicant argues that Larson does not teach a piercing mandrel "further including a conical sealing portion adjoining the cylindrical portion and widening to the lid portion." However, as discussed in the rejection above, Larson reasonably suggests this feature.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
8 September 2010